UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,426	09/23/2003	Bahar Reghabi	047711-0321	4240

23392 7590 10/09/2008

FOLEY & LARDNER
2029 CENTURY PARK EAST
SUITE 3500
LOS ANGELES, CA 90067

EXAMINER	
PATTON, AMANDA K	
ART UNIT	**PAPER NUMBER**
3762	

MAIL DATE	DELIVERY MODE
10/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,426	REGHABI ET AL.	
	Examiner	Art Unit	
	Amanda Patton	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment dated July 16, 2008 has been acknowledged. Currently claims 1-61 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-42, 49-52, and 54-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The phrase "wherein the power supply for each implantable sensing element is configured to supply power independent of the power supply for each other implantable sensing element" of claim 1, lines 16-18, claim 26, lines 17-19, and claim 42, lines 8-10 does not find support in the specification. Applicant refers to paragraphs [0032] and [0037] of the originally filed specification, but neither these paragraphs nor elsewhere in the specification is the limitation that the power supply of each implantable sensing element be configured to supply power independent of the other implantable sensing element given. The specification simply states that each implantable sensor includes "an analog-to-digital (A/D) converter integrated

circuit as well as a power supply for powering the integrated circuit, such as, for example, a capacitor". No relationship is given in the specification that each individual power supply supplies power to its respective sensing element individually and independently.

The phrase "and configured to supply power solely to the implantable sensing element of the plurality of sensing elements;" of claim 1, lines 18-19, claim 26, lines 19-20, and claim 42, lines 9-10 do not find support in the specification. Applicant refers to paragraphs [0032] and [0037] of the originally filed specification to find support for individual power supplies, but neither in these paragraphs nor elsewhere in the specification is a respective power supply that supplies power **solely** to an individual implantable sensing element. This statement is a negative limitation/exclusionary proviso that is not supported by the specification. See MPEP 2173.05i.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-41, 49-52, and 59-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1, lines 4-6, and Claim 26, lines 3-5 recite the phrase "each implantable sensing element of the plurality of implantable sensing elements operable though electrical communication with an external controller via an individual interconnect." The word "individual" is unclear, as it is not known if this phrase means that there is only one *total* interconnect between all of the sensors or one interconnect between each of the sensors and

the external device in a daisy-chained configuration, thus each sensor having its own interconnect.

Examiner wishes to note the inclusion of the phrase "individual" in all of the claims does not add any structural limitation, as the claims are comprising claim and do not preclude the use of more than one interconnect between each of the sensors or the external device. If Applicant wishes to include other structural limitations as to the connection of individual sensors to each other or to an external controller such limitation must be placed in the claims if supported by the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8, 9, 11-12, 26, 30-31, 33, 42, and 55-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Gord et al. (USPN 5,999,848, as previously cited).

Regarding **claims 1-4, 12, 26, 42, and 55-58**, Gord discloses the claimed method including:

- implanting an implantable sensor at a single site in a patient, (e.g. Figs. 1–4; Col. 7, lines 28–32; Col. 8, lines 35–36), wherein the implantable sensor has a housing within which are disposed a plurality of implantable sensing elements (e.g. Figs. 3A–5C) and wherein the implantable sensing elements are operable though electrical communication with an external

controller via an interconnect (e.g. daisy chained interconnects 14 and 16; Figs. 1-4) and wherein each implantable sensor comprises a respective power supply (e.g. capacitor 40 that supplies power to integrated circuit 38 for controlling the sensor; Fig. 3A; Col. 7, lines 58-65),

- reading an output from at least one of the implantable sensing elements (e.g. column 7, lines 34–41),
- evaluating a patient based on an output read from at least one implantable sensing element (e.g. column 7, lines 36–53);
- wherein a plurality of parameters are read from an implantable sensor at a single site (e.g. column 7, lines 31–34; column 13, lines 23–25),
- evaluating the patient based on the output read from the sensor and administering therapy to a patient based on an output read from at least one implantable sensing element (e. g. column 7, lines 44–45 and 51–53 wherein regulation of the insulin infusion is the therapy being administered).
- wherein at least one of an implantable sensing elements is a biological parameter sensor, a physiological parameter sensor, an analyte sensor (e.g. column 7, lines 30–34).
- and wherein an output read from at least one of the implantable sensing elements is a quantifiable value (e.g. column 7, lines 33–34 and 45–48);

Examiner wishes to note that since the claim is a comprising claim, it does not preclude the use of more than one interconnect between each of the sensors or the external device.

Regarding **claims 8, 9, and 11, 30-31, and 33**, Gord additionally teaches an implantable sensor method wherein reading/evaluating a patient based on an output from at least one of an

implantable sensing elements comprises reading an output from an implantable sensing element that responds to glucose (e.g. column 7, lines 30–33 and 45–48), temperature (e.g. column 7, lines 30–34), or pH (e. g. column 7, lines 30–33).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-7, 10, 13-25, 27-29, 32, and 34-41, are rejected under 35 U.S.C. 103(a) as being unpatentable over Gord.

Regarding **claims 5-7, 10, 13-25, 27-29, 32, 34-41**, Gord discloses the claimed invention but does not disclose expressly reading/evaluating a patient based on an output from at least one of the implantable sensing elements comprises reading an output from an implantable sensing element that responds to lactate, blood oxygen saturation, blood pressure, and potassium; and administering therapy/evaluating the patient comprises administering therapy/evaluating the patient for myocardial infarction, myocardial ischemia, angina, adjusting a function and placement of an implantable cardiovascular defibrillator disposed within the patient, sepsis, septic shock, a patient receiving extracorporeal membrane oxygenation, a patient undergoing cardiac bypass, a patient during dialysis; and classifying a severity of a condition of a patient based on an output read from at least one implantable sensing element; and a patient is in a surgical and an intensive care environment; and implanting an implantable sensor at a single site

in a triage patient and in a patient in the field. It would have been an obvious matter of engineering design choice to a person of ordinary skill in the art to modify the implantable sensing elements to sense/evaluate the biological and physiological parameters and administer/evaluate therapy to a patient as taught by Gord, to include those parameters and therapies listed in the claimed limitations above, because Applicant does not disclose that these limitations provide an advantage or solves a stated problem over and above the like/similar claimed limitations listed in the 35 U.S.C. 102(b) rejection over Gord above. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the claimed limitations as taught by Gord, because each of these sensors are configured to sense a different parameter and any configuration of an implantable, daisy-chainable device allows one or more, e.g., multiple, sensors to be employed within the device, with the data sensed by each sensor being convertible to an appropriate form and transferable through conductors to perform a desired medical function as needed for the benefit of the patient. Therefore, it would have been an obvious matter of design choice to modify the invention of Gord to obtain the invention as specified in the claims listed above.

In the alternative, for the above mentioned sensing elements, therapy, and the environment and location of a patient it is well known in the art for sensing elements to respond to lactate, blood oxygen saturation, blood pressure, etc., and to administer therapy for myocardial infarction, myocardial ischemia, angina, etc., and for patients to be in surgery, triage, etc. for the purpose of providing a myriad of beneficial and appropriate therapies to patients efficaciously and expeditiously in a variety of conditions and settings. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of

Gord to include the claimed limitations above for the purpose of providing a myriad of beneficial and appropriate therapies to patients efficaciously and expeditiously in a variety of conditions and settings.

Claims 43-54 and 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gord in view of Beranek et al. (USPN 4,608,986).

Regarding **claim 43-54 and 59-61,** Gord discloses the claimed invention except teach implantable sensing element attached to an external controller independently via an interconnect. Beranek discloses that it was well known in the art at the time the invention was made to attach implantable sensing elements to an external controller via individual interconnects (e.g. wire conductors 61-64 that attached electrodes 40-43 to the pacemaker, wherein each of the electrodes can be replaced with a physiological sensor such as an oxygen sensor; Figures 1-4; Col. 5, lines 13-16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the parallel connection of sensors of Beranek in the device of Gord, since such a modification would provide the system with the ability to connect the sensors to the external controller without connection with each other for providing the predictable results of sensors that will individually work regardless of whether another sensor stops functioning.

Response to Arguments

Applicant's arguments with respect to claims 1-58 have been considered but are moot in view of the new ground(s) of rejection as necessitated by amendment.

In response to Applicant's assertion that the phrase "each implantable sensing element of the plurality of implantable sensing elements operable through electrical communication with an external controller via an individual interconnect" is not unclear and is simply a generic claim, Examiner wishes to point out that the claim has not been rejected for being a generic claim, but has rather been rejected because electrical communication between the external controller and the implantable sensing elements is unclear. The word "individual" is unclear, as it is not known if this phrase means that there is only one *total* interconnect between all of the sensors or one interconnect between each of the sensors and the external device in a daisy-chained configuration, thus each sensor having its own interconnect.

In response to Applicant's argument that Gord does not disclose the newly added limitation of claims 1, 26, and 42, Examiner points to the rejection above and in particular to capacitor 40 that supplies power to integrated circuit 38 for controlling the sensor as described in Gord.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AKP/
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762